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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/380,086	11/29/99	PEREZ	P BET-99/0730

000466 HM22/0112  
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EXAMINER

KUBELIK, A

ART UNIT	PAPER NUMBER
1638	10

1638

10

DATE MAILED:

01/12/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

# Office Action Summary

Application No.

09/380,086

Applicant(s)

PEREZ ET AL.

Examiner

Anne Kubelik

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1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 29 November 1999.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claims 1-12 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

## Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: \_\_\_\_\_

***Election/Restrictions***

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1-2 and 5, drawn to use of a plant with cytoplasmic male-sterility for avoiding dissemination of a transgene.

Group II, claims 1, 3, and 5, drawn to use of a plant with nuclear male sterility for avoiding dissemination of a transgene.

Group III, claims 4 and 6-9, drawn to use of an artificial male sterility gene for screening transformed plants, plants thereby obtained, and a vector and cell used in the process of transformation.

Group IV, claims 10 and 12, drawn to a process and a kit for eliminating an excisable DNA fragment.

Group V, claim 11, drawn to a process for producing an expression product of a transgene.

Claims 1 and 5 will be examined to the extent they read on the elected invention.

The inventions listed as Groups I-V do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: These inventions do not constitute an advance over the prior art. Odell et al (WO 91/09957) describe the application of the *loxP-cre* recombination

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system for controlling male fertility, which would avoid dissemination of transgenes (pg 19-20), and the use of the system in deletion of a marker gene (pg 60-66). Oliver et al (WO 96/04393) describe the use of a recombinase system to excise a male-sterility gene (pg 10-11).

These groups are deemed to lack unity of invention because they are not so linked to form a single general inventive concept. Because the inventions do not share a single male sterility gene, the methods of use of the male sterility genes are not linked. Thus, the use of an artificial male sterility gene for screening transformed plants (claim 4) is not linked to the process for eliminating an excisable DNA fragment (claim 10) or to the process for producing an expression product of a transgene of interest (claim 11).

Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation. The use of a plant with a cytoplasmic male sterility gene of invention I requires different promoters and methods of transformation than does the use of the plant with a nuclear male sterility gene of invention II.

Inventions I and II are unrelated to invention III. The different inventions have different modes of action and different effects. The uses of the plants of inventions I and II for avoiding dissemination of an integrated transgene requires methods of assaying progeny plants not required by the use of an excisable artificial male sterility gene to screen for plants that have excised a DNA fragment in invention III. Furthermore, the use of invention III requires methods of screening for loss of a DNA fragment, not required by inventions I and II.

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Inventions III, IV and V are unrelated to each other. The process of eliminating an excisable DNA fragment of invention IV requires methods of crossing and plants carrying recombinase or transposase genes not required by the process of producing an expression product of invention V or by the use of an artificial male sterility gene of invention III. Additionally, invention V requires methods of protein assaying and purification not required by either invention IV or III. Invention III requires methods of assaying for linkage of an artificial male sterility gene to a gene of interest not required by either of inventions IV or V.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and fields of search, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne R. Kubelik, whose telephone number is (703) 308-5059.

The examiner can normally be reached on Monday through Friday, 8:15 am - 4:45 pm.

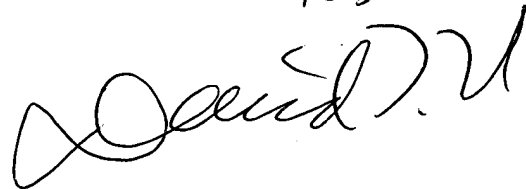
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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Paula Hutzell, can be reached on (703) 308-4310. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Anne R. Kubelik, Ph.D.  
January 10, 2001

DAVID T. FOX  
PRIMARY EXAMINER  
GROUP ~~180~~ 1638

A handwritten signature in black ink, appearing to read "David T. Fox", written over the printed name and group number.